



Lewis G. Zirkle Jr., M.D. President

Dear SIGN Partner:

SIGN is delighted to present you with this IM Nail & Interlocking Screw Set. This set is designed for use in treating patients who need but cannot afford an IM nail and interlocking screw system. SIGN intends to provide you with the highest quality orthopaedic instruments and implants. SIGN implants are made from stainless steel that satisfies ASTM implant-grade material specifications acceptable to the U.S. FDA. Our orthopaedic hardware manufacturing operation is being conducted in accordance with national good manufacturing practices and quality assurance standards. The SIGN IM Nail is a legally distributed device in the United States.

The SIGN Surgical Database was implemented in August 2003 to record SIGN surgeries. We request that each SIGN surgery be recorded in the database, photos of pre and post op x-rays are requested to accompany each report.

We value your comments on any aspect of SIGN. It is a team effort. We can be reached by e-mail, fax, or telephone.

The SIGN technique manual is updated frequently. For updates please visit our website at <u>www.sign-post.org</u> and click on manual, username **sign** and password **03signtech**. Please read this manual several times before your first SIGN surgery. Refer to it for each step in the OR as you do your first surgeries.

Sincerely,

Lewis g. Juble, Jr. M.D.

Lewis G. Zirkle Jr., MD SIGN Founder & President

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

SIGN Reusable Surgical Instruments

DESCRIPTION: SIGN Surgical Instruments are available for humerus, `tibia and femur fractures. Proper care and inspection of each instrument is critical before and after each use.

INFORMATION FOR USE: SIGN's Instruments are reusable; however, they have a limited life span. Prior to and after each use, the instruments must be inspected where applicable for sharpness, wear, damage, proper cleaning, corrosion and integrity of the connecting mechanisms. Notify SIGN if they should be replaced.

WARNINGS: For safe and effective use of any SIGN instrument, the surgeon must be thoroughly familiar with the instrument and the recommended surgical technique. Instrument breakage or damage can occur when an instrument is subjected to excessive loads, speeds, or dense bone.

CLEANING: SIGN instruments and accessories must be thoroughly cleaned before reuse. Decontamination of reusable instruments should occur immediately after completion of the surgical procedure. Excess blood or debris must be wiped off to prevent it from drying onto the surface. Use an enzymatic-cleaning product such as Enzol.

NOTE: Even surgical instruments manufactured from high-grade stainless steel must be dried thoroughly to prevent rust formation. All devices must be inspected for cleanliness of surface, joints, and proper function, and wear and tear prior to sterilization.

STERILITY: All instruments are provided non-sterile. Sterilization may be performed using one of the following methods. For gravity displacement autoclave, set at 250° F (121° C) for 30 minutes. For a prevacuum autoclave, set at 270° F (132° C) for 4 minutes, or at 273° F-279° F (134° C to 137° C) for 3 minutes. Please consider your equipment manufacturer's written instructions for the specific sterilizer and load configuration being used and current AORN standards and recommended practices. The equipment must be entirely disassembled prior to sterilization.

STORAGE INSTRUCTIONS: Store in a cool, dry place, and keep away from direct sunlight.

SHARPENING: The drill bits become dull if they are dinged by hitting the nail or other metal. They should be protected during surgery, cleaning and sterilization. They are also dulled by pushing drill bits into bone when they are not advancing. The drill bit heats up and becomes dull.

SIGN STANDARD IM NAILS

DESCRIPTION: SIGN intramedullary nails and screws are designed to provide fixation of humerua, tibial and femoral fractures while they heal.

INFORMATION FOR USE: Physiological dimensions limit the sizes of implant appliances. The surgeon must select the type and size that best meets the patient's requirements. SIGN sets containe the following SIGN IM Nails; 8-12mm Dia., 200-420mm Long.,

INDICATIONS: The SIGN IM Nail is indicated for internal fixation of diaphyseal tibial fractures humerus fractures and femur fractures including transverse fractures, oblique and spiral fractures, comminuted fractures, fractures with bone loss, open fractures which are clean enough to close, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions and fractures in the proximal femur.

CONTRAINDICATIONS: Active or latent infection. Wounds in the leg should be closed and dry. Insufficient quantity or quality of bone/soft tissue (based on judgement of surgeon). Patients who are unwilling or incapable of following postoperative care instructions.

WARNINGS: For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant and the recommended surgical technique for this device. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening and migration. The patient must be cautioned, in writing, about the use, limitations, and possible adverse effects of this implant, including the possibility of the device failing as a result of loose fixation and/or loosening and excessive activity before the fracture has healed. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail.

PRECAUTIONS: A Nail or Screw implant should not be reused. Previous stresses may have created imperfections which can lead to device failure. The threads in the nail and tabs may have been damaged by prior use. Instruments shall be inspected for wear or damage prior to usage. Protect implant appliances against scratching and nicking.

ADVERSE EFFECTS: These include breakage of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, excessive force exerted on the implant during insertion, implant migration and/or loosening, metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material, pain or discomfort may occur due to the presence of an implant. Nerve damage, necrosis of bone or bone resorption, necrosis of tissue or inadequate healing may occur with any fracture.

STERILITY: All implants are provided *non-sterile*. Sterilization must be performed prior to surgery, using one of the following methods. For a gravity displacement autoclave, set at 250°F (121°C) for 30 minutes. For a prevacuum autoclave, set at 270°F (132°C) for 4 minutes, or at 273°F - 279°F (134°C to 137°C) for 3 minutes. Please consider your equipment manufacturer's written instructions for the specific sterilizer and load configuration being used and current AORN standards and recommended practices. The equipment must be entirely disassembled prior to sterilization.

STORAGE INSTRUCTIONS: Store in a cool dry place, and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, damage, or water contamination.

INDICATIONS FOR SIGN NAIL

FRACTURE TYPE

a. Closed at time of injury

Fractures that cannot be reduced or lose reduction.

b. Open-acute

Fractures that are Gustilo grade I, II, IIIa, debrided and closed within 24 hours of injury may have immediate SIGN nail insertion. Sometimes this time limit is impossible, so we must study the elapsed time between injury and surgery if antibiotics are given within 6 hours from injury. If closure is delayed, the surgeon should determine when the SIGN nail is placed at wound closure.

c. Open-delayed closure

Debrided and covered by skin, muscle or free flap, with no drainage, may have SIGN nail insertion.

d. Fractures treated by external fixation

Such fractures should have insertion of SIGN nail within 10 days of placement of external fixation. Risk of infection is increased if external fixation pins are present for over 10 days. (We are studying this)

e. Non-unions

PATIENT PREPARATION

Patient must have no infected areas or injuries that preclude surgery. Patient should be told about risks, benefits of surgery and agree to insertion of SIGN nail. Please check the patient's skin the night before surgery. If possible, washing the patient's leg should be done the night before.

Check list for the night before surgery

- 1. Any infections? Where?
- 2. Skin of extremity washed well.
- 3. Range of motion of knee.
- 4. Template X-Rays to estimate size of nail, screws.
- 5. X-rays to be in OR.
- 6. Check appropriate lab work.

SURGEON PREPARATION

Read the technique manual and /or watch the technique CD. Think about your technique.

X-RAYS

X-rays should include knee and ankle on the same film to measure the nail. The width of the nail should be the same size as the narrowest area of the medullary canal, usually on lateral x-ray view. X-rays should be present in OR during surgery. Look carefully for fracture comminution.

ANTIBIOTICS

Antibiotics are started 1 hour before surgery.

OPERATING ROOM EQUIPMENT

These materials, which are not part of the SIGN set, should be present in the operating room: drill; chuck key; mallet; bone holding forceps; knife; forceps; clamps; cautery; suction; towel clips; needle holders; sutures; retractors, deep and superficial reamers and curved awl.

All personnel must wear masks, hats, and cover as much skin as possible. Bacteria spread to the wound on skin cells from people in the operating room. Traffic in the OR should be minimal.

(SIGN) EQUIPMENT NECESSARY FOR USE OF SIGN NAIL:

- L-Handle
- Locking Bolt (2) one is extra
- Target Arm (Proximal Target Arm, Distal Target Arm)
- Short Target Arm (<u>for use with nails shorter than 280mm</u>)
- Cap Screws, Distal Arm (4) two are extra
- Shoulder Cap Screw (2) one is extra
- Combination Hex Wrench (2) one end fits the Locking Bolt, Shoulder Cap Screw and Distal Arm Cap Screws. The other end fits the interlocking screws.
- Cannula
- Alignment Pin (2)
- Drill Guides (2) (one large for large drill bits) (one small for small drill bits)
- Drill Bits
 - Large (2) (6.3mm) for near cortex
 - Small (2) (3.5mm) for both near & far cortex
- Screw Caddy and SIGN Interlocking screw assortment
- SIGN IM nail assortment
- Hex Screw Driver (3.5 mm)
- Extractor/Compressor Set
 - Extractor Rod Connector
 - Extractor/Compressor Rod
 - Slap Hammer Weight
- Slot Finders; Cannulated, Solid and Curved (one of each)
- 11 mm Wrench
- Tissue Protector (2) one is extra (<u>these are reusable</u>)
- Depth Gauge
- Step-Drill
- Screw Hole Broach

Care of SIGN Equipment:

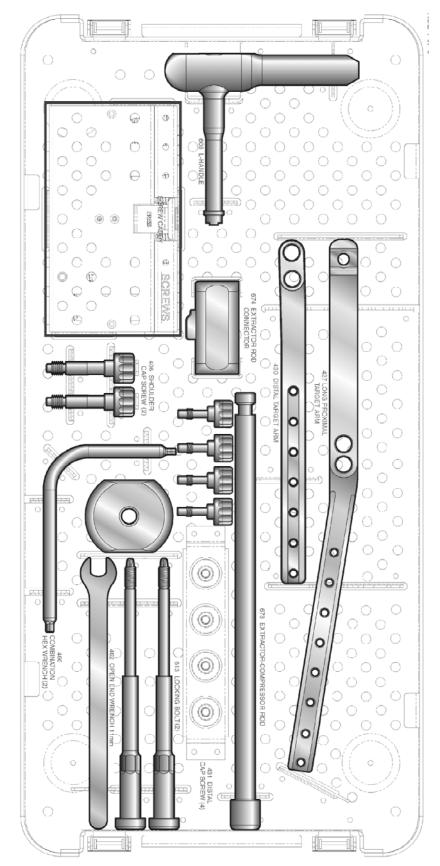
It is essential that the equipment be well maintained as described on Page 2. Sometimes during the surgery the cannula and drill bits become bloody. They should be washed off before the next interlock, as they may stick due to the close fit. This also applies to the threads of caps screws.

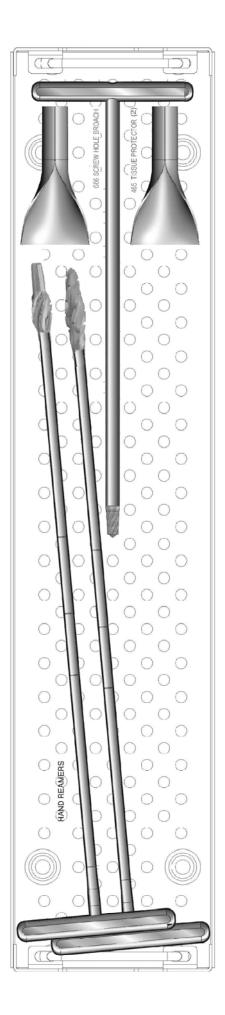
NOTE: Please protect the drill bits and step drill from striking metal objects during surgery and cleaning.

Be sure an assortment

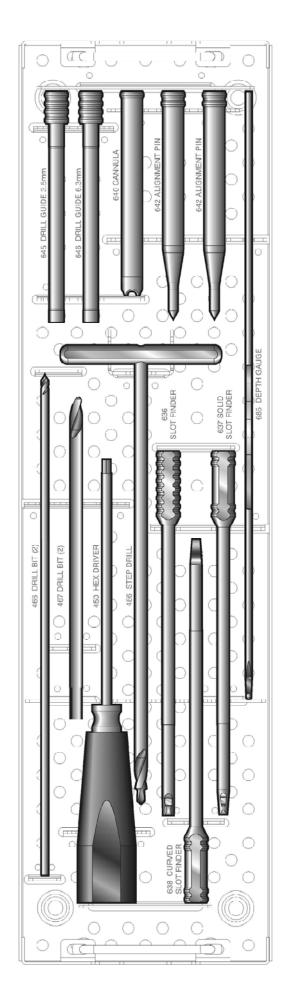
∕ of sizes is sterilized

SIGN Instruments

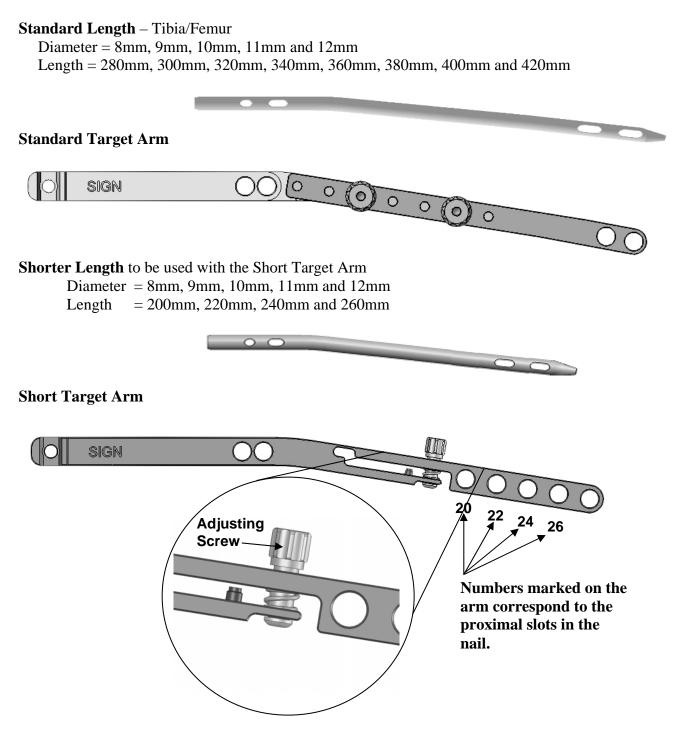








SIGN NAILS



Important: The adjusting screw is for fine adjustment only – moving the screw too far in or too far out may cause it to bind.

SIGN TIBIA NAILING TECHNIQUE

Position of Patient

Supine -100° of knee flexion is needed. This can be obtained by flexing the OR table, using a sterile bump or triangle under the thigh or a triangle to hold the knee in flexion, figure 4 position may also be used.

If open reduction is necessary, do before the incision for the nail. If closed reduction, check the stability of the fracture in all directions before the reduction is attempted. This will give you a baseline to test the stability to determine if the reamers are in the distal fragment.

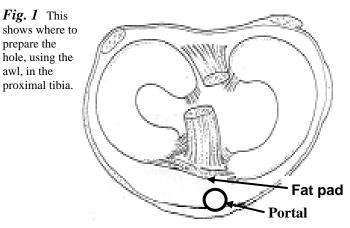
Skin Incision

Incision is made through patellar tendon to allow entrance through the patellar tendon. Some use an incision medial or lateral to the patellar tendon.

Bone Entrance

Do not enter the fat pad. A curved awl is used to make the bone entrance hole. Direct the awl anteriorly especially if the fracture is in

the proximal tibia. Hold the proximal fragment in $90^{\circ} - 110^{\circ}$ flexion.

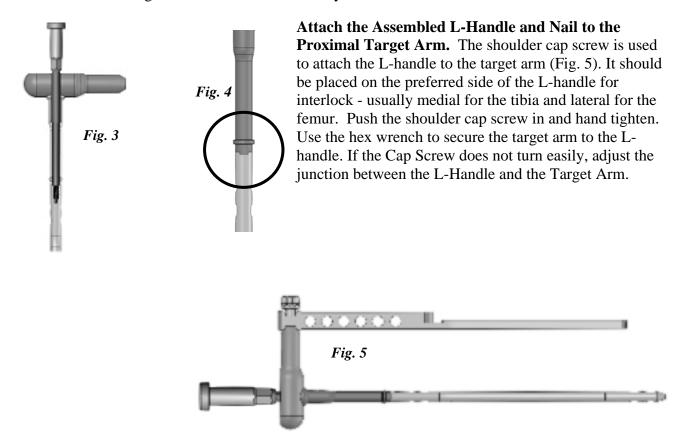


Reaming

Use the small reamer to connect the

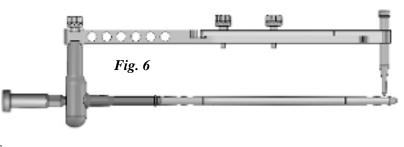
entrance hole with the canal. Direct the reamer anteriorly. Flex the knee to 100° if needed. Save the bone graft that collects in the reamer flutes and that removed when reamer is removed. Ream until chatter then use a nail 1 or 2 mm smaller. Length is determined by measuring the tibia at time of surgery or before surgery on the other leg. Sometimes a blocking screw (Fig. 9) is needed to direct the reamers, but I prefer to insert this reduction aid after reaming so the reamers are not dulled.

Assemble the Nail. Insert the locking bolt through the hollow stem tube of the L-handle until the threads are visible at the bottom of the stem tube (Fig. 3). **NOTE:** Be sure the locking bolt rests as far down the stem tube as possible. Thread the bolt into the IM nail. Carefully align the notches in the nail to the corresponding protrusions on the stem tube of the L-handle (Fig. 4) and tighten with the wrench. It is best to align the notch of the L-handle and nail before threading the locking bolt through the nail. This prevents cross threading. One person should hold the nail-L-handle junction and one should turn the locking bolt or rest the nail vertically on the OR stand.



Attach The Distal Target Arm To The Proximal Target Arm. Place the alignment pin through the end hole in the distal target arm and distal slot in the nail (Fig. 6). The cap screws are now placed to connect the proximal and distal target arms, leave holes between the two cap screws for stability. Withdraw the alignment pin so only the tip is in the slot to check alignment of the target arm as the cap screws are hand tightened, tighten each screw a little at a time, final tightening by Hex Wrench. Recheck alignment of alignment pin to the slot.

• The cap screws are inserted easier if they are inserted in downward direction so the target arm and cap screws are perpendicular to the floor. Removal is the reverse – but perpendicular to the floor. This avoids stripping the cap screw threads.



<u>NOTE</u>: If you are using the Short Target Arm, turn the adjusting screw with the hex wrench until the alignment pin properly aligns with the distal hole of the nail.



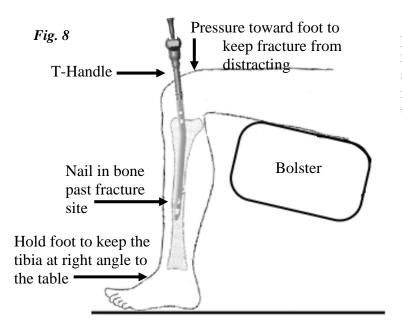
Remove The Target Arm From The L-Handle. Leave the L-handle attached to the nail (Fig. 7).

Insertion of the Sign IM Nail

1. Insert the IM Nail into the hole in the proximal tibia. Be sure you are aligned in the bone canal. Use the tissue protector so the nail does not touch the skin.

2. In a proximal tibia fracture a blocking screw may be necessary to direct the nail down the canal of the proximal fragment (Fig. 9). The proximal fragment must be held in 110^{0} flexion during reaming and nail insertion.

3. Push the nail down the canal. If it stops, <u>tap gently three or four</u> <u>times, then rotate the nail 10° to be sure it is in the bone canal.</u> The 1.5° bend in the end of the nail helps prevent penetration of the cortex as it is rotated. If you hammer the nail in without twisting, the nail may get stuck in the canal. <u>Be sure the locking bolt</u> <u>connecting the L-handle to the nail does not loosen as the nail is</u> <u>advanced</u>. Tighten the locking bolt as necessary.

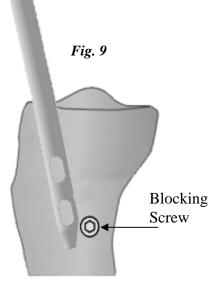


3. Put the IM Nail down as far as possible toward the ankle joint. After the nail passes through the fracture site, stabilize the foot on the OR table to maintain reduction without distraction as the nail is advanced (Fig. 8).

Blocking Screws

The purpose of blocking screws is to direct the nail so that it exits the proximal fragment in the canal. The blocking screws are most commonly used in proximal tibia fractures to prevent the nail from penetrating the posterior cortex. This may occur due to soft bone, comminuted posterior cortex, or when the knee cannot be flexed to 100°. The screw is placed medially/laterally through the posterior cortex to direct the nail (Fig. 9).

The blocking screw is also used in proximal tibia fractures when the proximal fragment goes into valgus or varus. The screw is directed so that better reduction is obtained. This time the screw goes from anterior to posterior to direct the nail in the medial/lateral plane. Place the blocking screw where you don't want the nail to go.



Re-Attach Target Arm to L-Handle

You are now ready to place distal interlocking screws. Be sure the locking bolt connecting the L-handle to nail is tight (Fig.10).

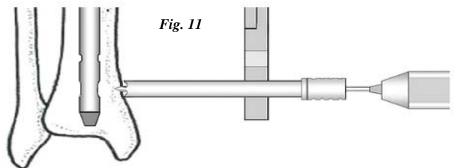
Insertion of Interlock (Distal)

1. Distal interlock should be done before proximal interlock so the nail can be rotated to change orientation of the slot for screw insertion. Use the alignment pin to mark the location of the skin incision.

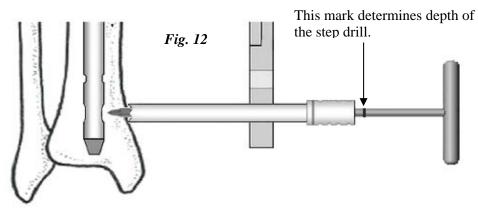
2. Dissect down to the bone with a periostial elevator to remove all soft tissue from the bone. Place the cannula through the incision down to the bone using a clamp to spread the tissues and remove soft tissue from under the cannula. Tight fascial bands must not displace the cannula.

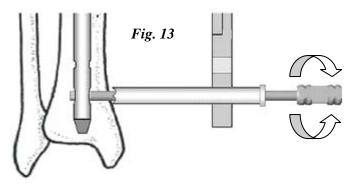
3. Insert the small drill guide into the cannula. Using the small drill bit, drill the hole in the near cortex (Fig. 11). Change small drill guide to the large drill guide and use the step drill to enlarge the hole in the near cortex (Fig. 12). The large drill bit may also be used if the bone is too hard for the step drill.





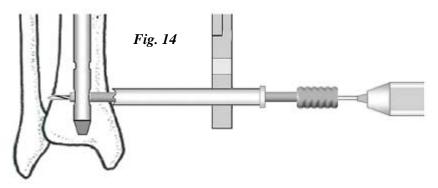
<u>NOTE</u>: When the step drill stops suddenly it is in the slot of the nail. If you force it, the tip will break.



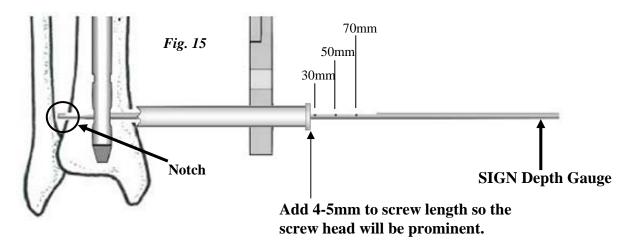


4. Insert the solid slot finder into the cannula. The solid slot finder is stronger and has a narrower tip than the cannulated slot finder. The solid slot finder is aligned using the flat part with the plane of the nail. It is then pushed into the slot of the nail. It is not placed by rotation. The "SIGN feel" can be demonstrated when the slot is in the nail. (i.e. 10° rotation either way) (Fig. 13). If the slot finder does not rotate at all it is only partially inserted into the slot in the nail so

rotate the nail using the L-handle. If the slot finder rotates 360°, it is not in the slot, rotate the nail to help find the slot finder in the slot. If the slot finder enters the slot in the nail replace it with the cannulated slot finder and drill a hole in the far cortex (Fig. 14). If the solid slot finder does not enter the slot in the nail there may be bone either in the near cortex hole or in the slot in the nail, or the hole may be mal-directed. Check the hole and use the screw hole broach to clear the hole. The slot finder is placed by pushing on it with the flats oriented to the axis of the nail. Only slight rotation is necessary.

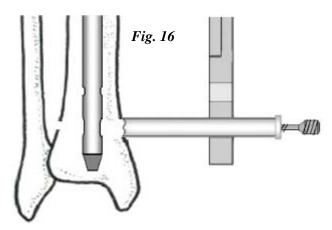


5. After the cannulated slot finder is in the slot of the nail, insert the depth gauge through the cannulated slot finder. Remove the cannulated slot finder. The cannula is used to read the depth gauge (Fig. 15).

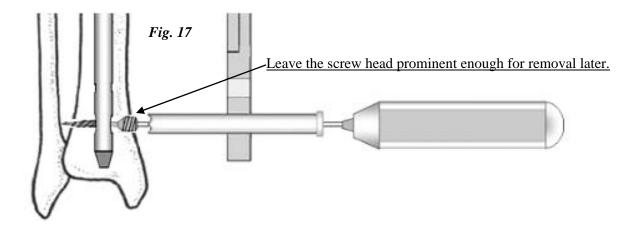


Dance around the hole with the depth gauge until you get a solid hold on the outer far cortex

6. Keeping the cannula over the hole in the near cortex push the screw through the hole in the near cortex and slot in the nail. You will feel the screw threads go through the slot then screw it into the far cortex (Fig. 16). The head of the screw should be left prominent for later removal.

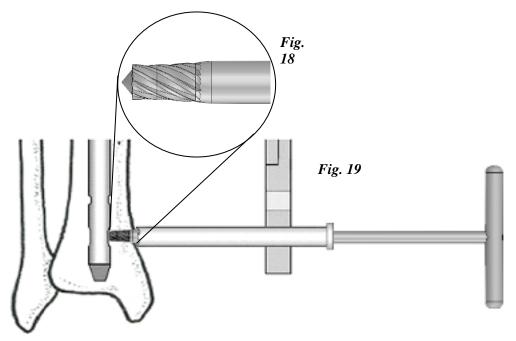


7. Move the cannula back so that you can be sure the screw is not inserted too far into the near cortex (Fig. 17). Go to step 4 on Page 19.

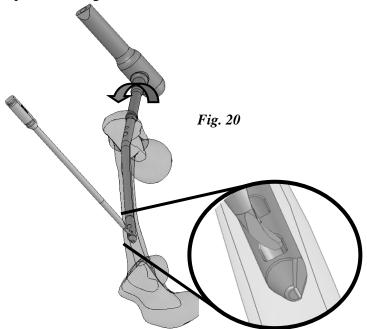


If the Slot Finder Will Not Enter the Slot of the Nail, Proceed as Follows:

1. Remove the cannula and target arm. Check to see if the hole is completely drilled. If the hole contains bone at the base, use the screw hole broach (Fig. 18) to complete the drilling of the hole (Fig. 19). If the SIGN feel is felt, use the cannulated slot finder.



Place the curved slot finder through the near cortex hole and seek the nail slot (Fig. 20). If the curved slot finder enters the nail slot incompletely, **rotate the nail**. If the curved slot finder goes into the nail slot, you will feel the "SIGN feel." Proceed with using the solid then cannulated slot finder. Do not replace the target arm until the distal screw is in. If the curved slot finder does not enter the hole by



rotating the nail, check to see if the fracture reduction has slipped. If not, check to see if the nail has moved longitudinally in the canal.

2. Once the cannulated slot finder is in the slot, place the depth gauge to mark the holes in both cortices. Remove the slot finder and place the cannula so the screw length can be measured.

3. Insert the screw.

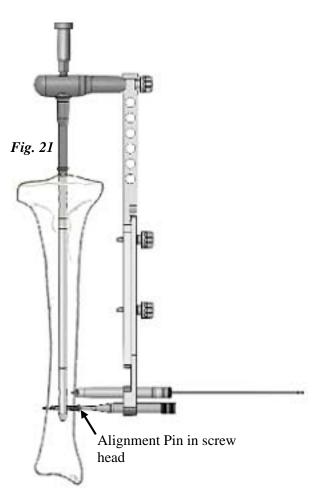
4. You can determine if the distal interlocking screw is through the slot in the nail by rotating the L-handle.

5. After the first screw has been placed, place the foot upon the table and make sure that the fracture site is impacted before proceeding with the second distal screw. (See Fig. 8) Or, you may use the extractor compressor to compress the site (Fig. 22).

6. Replace the target arm.

7. Place the alignment pin into the head of the distal screw and ask an assistant to keep it there (Fig. 21).

8. Place the second distal screw.



If you place the cannula in and it rest too anteriorly, loosen the Distal Target Arm so the hole is drilled to enter the canal. The Nail slot will be easy to find by rotation.

Fracture Compression (As Needed)

After the distal interlocking screws have been placed, attach the extractor/compressor on the locking bolt. The slap hammer weight can then be used to back slap the fracture site and compress it (Fig. 22). (See Nail Extraction Version Two for assembly instructions on Page 22).



Insertion of Interlock (Proximal)

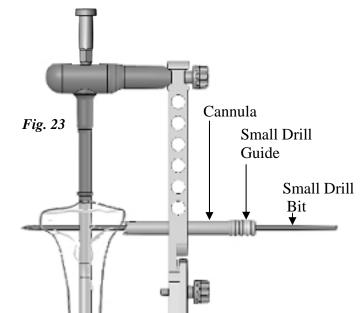
1. The target arm should now be firmly attached to the L-handle.

2. Insert the alignment pin tip to the skin to mark the location of the skin incision.

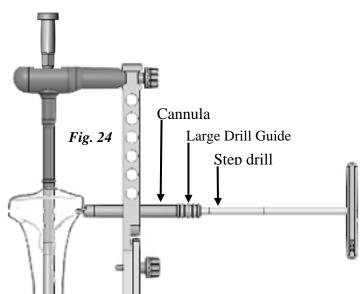
3. Make skin incision.

4. Clear soft tissue off the bone. Place the cannula next to bone.

5. Use the cannula, small drill guide and small drill bit to drill a hole through the near cortex and far cortex (Fig. 23).



<u>NOTE</u>: The slot finder is not necessary to find the nail slot for proximal interlock.



6. The large drill guide and step drill are used to enlarge the hole in the near cortex (Fig. 24).

7. The depth gauge determines screw length (Fig. 15).

8. Insert the screw.

9. Remove the cannula to view the head of the screw so it doesn't go too far. Remember someday the screw may need to be removed.

10. Place two proximal screws.

After the fracture is well fixed by the SIGN IM nail and proximal and distal interlock screws, remove the L-handle from the nail.

Irrigate the wound and place bone graft.

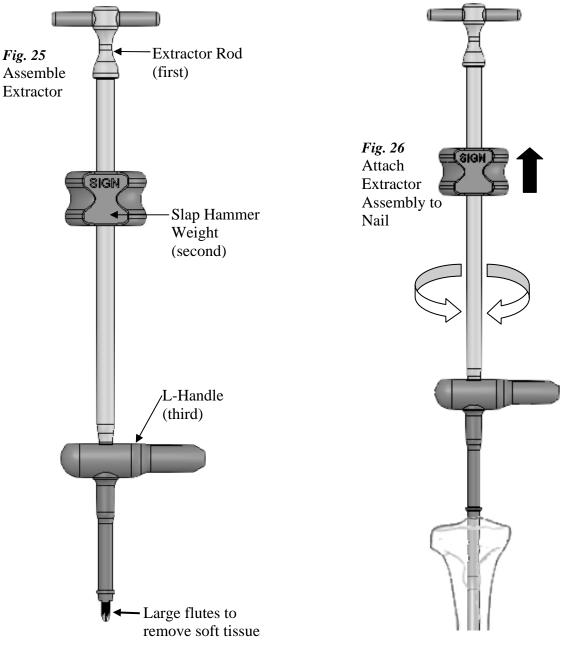
NAIL EXTRACTION (VERSION ONE)

NOTE: NEVER EXTRACT THE SIGN NAIL BY STRIKING THE L-HANDLE

The extractor tip is designed to remove soft tissue that may have grown into the end of the nail. The SIGN extractor technique uses rotation as well as distraction to remove the nail. The extractor is inserted through the L-handle.

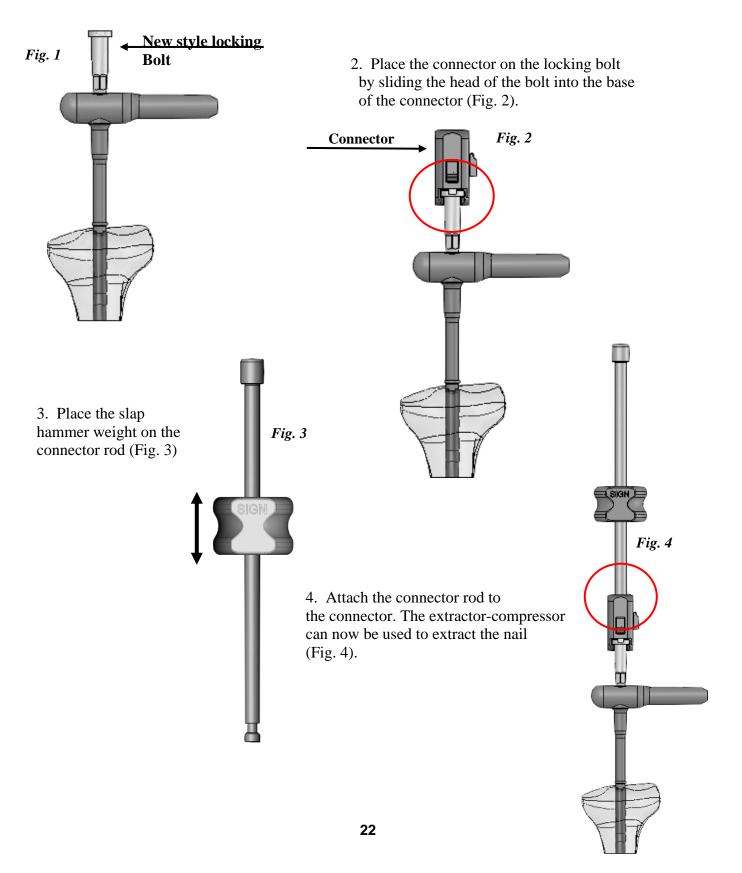
Steps for Use: Refer to (Fig. 25) and (Fig. 26)

- 1. Put the slap hammer weight on the extractor.
- 2. Put the extractor through the L-handle.
- 3. Thread the extractor tip into the nail. <u>Be sure the tabs on the nail are tightly opposed to the tabs on the L-handle.</u>
- 4. Extract the nail using the slap hammer and rotation of the L-handle.



NAIL EXTRACTION (VERSION TWO) - EXTRACTOR/COMPRESSOR

1. First, make sure the new locking bolt is connected tightly to the nail through the L-handle (Fig. 1).



SIGN <u>RETROGRADE FEMORAL</u> NAILING TECHNIQUE

Terms

(See Fig. 1)

Indications

Pregnant patient, bilateral femur fractures, anesthesia considerations, acetabular fractures, fractures in the distal half of the femur.

Position

Patient should be supine. If the OR table can gatch so some knee flexion is allowed, positioning is easier. This is not absolutely necessary. Knee flexion necessary is 60°, but more flexion allows better visualization of the entrance hole. Additional flexion can be achieved using a sterile bump or a triangle to hold the knee in flexion.

Fracture Reduction

If open reduction is indicated, do this first. Hold the reduction during reaming and insertion of the nail. Reaming can be done in the proximal fragment through the fracture site.

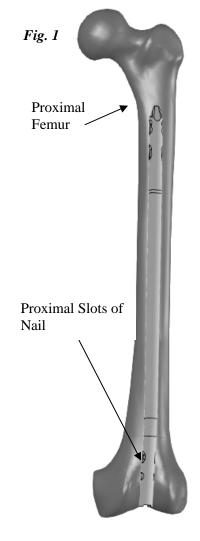
Make a small incision where you feel the fracture site is. The ideal incision is small and made at the end the stable (proximal) fracture fragment. Enter the fracture site by pushing your finger through or behind the posterior vastus lateralis. You will then understand the amount of trauma sustained in the injury by assessing muscle damage. Extend the incision by separating the muscle with a periosteal elevator.

Do not currett the bone ends except to remove obstructions to bone apposition. The bone ends contain osteoclasts, necessary in the healing process.

Reduce and stabilize the fracture reduction.

Soft Tissue Incision

Medial to the patellar tendon or through it. Medial approach is easier as the patella can be moved lateral to expose the bone entrance.



Bone Entrance

In the medial side of the knotch superior to the posterior cruciate attachment at the edge of the articular cartilage (Fig. 2). The entrance hole must be visualized by changing the amount of flexion of the knee. A curved awl makes the initial bone entrance. Stabilize the distal fragment as entrance hole is made.

Reaming

7 mm reamer is used from the bony entrance to the canal into the fracture site. Aim for the fracture site to avoid canal penetration. Progressive reaming is done until chatter occurs over a 6 cm section of femur. This indicates diameter of the nail. 2 sizes smaller than the chatter ream is the diameter of the nail. The reamer is rotated 360° during penetration as well as removal of the reamer.



Bone Graft

Save the bone from the flutes of the reamer (Fig. 3) and the bone that comes out of the entrance hole for bone graft. Save in a bone cup. Placing the bone in sponges leave bits of foreign material and saline kills bone cells.

Determine Size of Nail

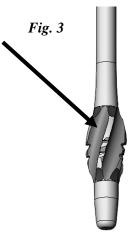
Nail diameter is 2mm less than the reamer diameter used when chatter occurs. The interlocking nail does not depend on canal-nail contact for stability.

Assemble Target Arm to the Nail

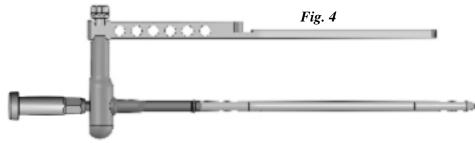
Orient the nail. Place the target arm on correct side for interlock.

Insert locking bolt through L-handle and screw it in.

Orient locking bolt perpendicular to floor and attach proximal target arm using shoulder bolt (Fig. 4). Do not force the threads or they will strip.



Place distal target arm with alignment pin through the distal hole. Line up the holes between the target arms and place the cap screws with 2 holes between them. Hold the alignment pin over the hole not in the hole as the cap screws are tightened for accuracy. Hand tighten each Cap Screw a little and then tighten the other one, tighten progressively. Final tightening is with the hex wrench. Detach the target arm from the L-handle.

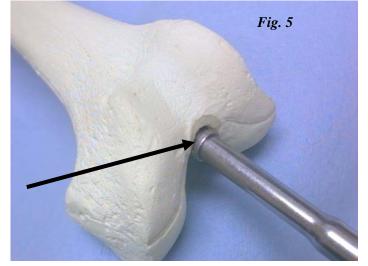


Nail Insertion

1. Tissue protector is used to keep the nail off the skin. Tissue protectors can be re-sterilized. **Do not discard them**.

2. The nail should be pushed in as much as you can. If the mallet is used, tap gently twice and twist the L-handle 10°. This rotation keeps the nail from becoming stuck in the canal and decreases the bending of the nail. Check the fracture site frequently during insertion of the nail.

3. Check the tightness of the locking bolt to the nail. The nail should be inserted so the ring rests on the articular surface of the

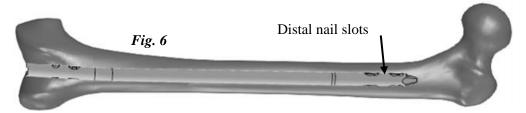


articular (Fig. 5). The nail will then be just below the articular surface.

Attach Target Arm to the L-handle

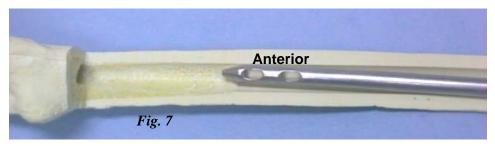
Distal Interlock

Distal interlock refers to slots nearest hip (Fig. 6). If you use one screw, choose the nail slot nearest the fracture site.



- 1. Use alignment pin to dimple the skin and mark the incision. If 2 screws are placed, make the initial incision for both.
- 2. Use periosteal elevator to pass through muscle fibers to the bone. Scrape periosteum, insert cannula so it sets on the bone. Curved clamp is used to free soft tissue under cannula. Tap the cannula.

 The final location of the slots in the distal nail depends on the curve of the femur and the force necessary to insert the nail. SIGN nail is a straight nail. If



it is inserted into the canal without a great deal of force, it will end up in the anterior portion of the femur (Fig. 7). The longer the nail, the more anterior. Adjust the Target Arm if the Cannula rests too far anterior

 If the nail is exerted with force it will bend and be more centrally located in the canal (Fig. 8). If the slots are in a narrow part of the femur, they will be



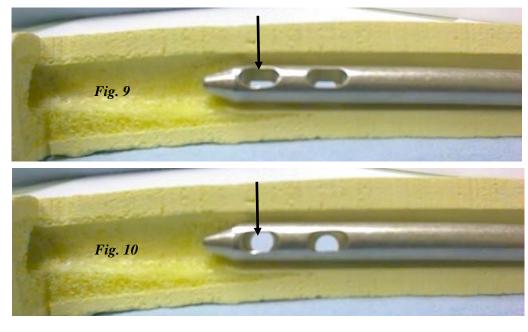
more central in the canal. The target arm may have to be adjusted to accommodate for bending of the nail. Loosen the Cap Screws and adjust the distal Target Arm.

- 5. Place the small drill guide through cannula. Use small drill bit to enter near cortex. Do not hit the nail or the drill bit will dull.
- 6. Replace small drill guide with larger one.

7. Use the step drill to enlarge the hole in near cortex. Be sure the tip is in the small hole before starting. When the step drill becomes harder to turn, it is either in the slot of the nail or just penetrating the inside of the hole. Retract the step drill and turn gently. If it rotates, continue until firm resistance. Firm resistance means the step drill is in slot of the nail. **Stop or the step drill will break!!!**

Screw hole broach can be used to remove the bone from the inside of the hole and enlarge the hole. It will not enter the slot in the nail.

(Fig.9) and (Fig. 10) illustrate the effect rotation has on the orientation of the slots. Rotation of the nail will place the slots in parallel with the hole in the near cortex. This is especially important with a curved slot finder.

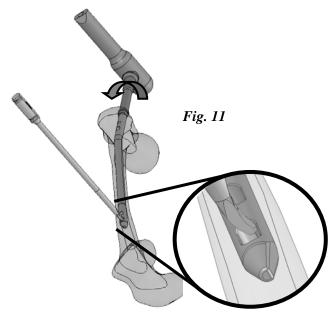


8. Insert the solid slot finder. Keep the flat of the handle in line with the nail. Push it in. Rotation will help it enter the slot.

9. The second SIGN feel is rotating the slot finder 10° when it is in the slot. If it does not rotate, it may be stuck in the bone hole or obliquely in the slot (Fig. 9). Sometimes

the L-handle must be rotated to orient the slot to the hole (Fig. 10).

10. When the solid slot finder demonstrates the SIGN feel, insert the cannulated slot finder. This has a wider end so may not enter the hole. Use the screw hole broach to enlarge the hole. When cannulated slot finder insertion has the SIGN feel, drill the small hole in the far cortex.



11. If either slot finder cannot be placed, remove the target arm and use the curved slot finder. Be sure the fracture has not shifted or the hole will not be in longitudinal orientation to the slot. Rotate the nail to orient the slot to the hole. Practice this using the nail when not in the bone or use a sawbones.

12. Once the curved slot finder is placed (Fig. 11), replace it with cannulated slot finder and drill the hole in the far cortex.

13. Place the depth gauge through the cannulated slot finder to mark the hole. Remove the slot finder and drill guide. Use the depth gauge and cannula to measure the screw length.

- 14. The screw should be 3-5mm longer than measured so the head can protrude for removal later. Raise the cannula to see how far the screw has entered the hole so the nail is not inserted too far. (See illustrations for using distal interlock in tibia section, Pages 15-19).
- 15. Test SIGN feel by rotating the L-handle to see if rotation is stopped by screw in slot.
- 16. Place alignment pin in the head of the screw to orientate the target guide.
- 17. Insert the second distal screw as you decide.
- **<u>NOTE</u>**: If you wish to compress the fracture site. Place one interlocking screw in the nail slot nearest the knee. The L handle is struck to move the distal fracture fragment toward the proximal fragment (Fig. 12). **<u>Different</u>** from the antegrade approach.



Proximal Interlock

Proximal interlock for retrograde femur refers to nail slots nearest to the knee.

- 1. Place cannula on bone as in distal interlock.
- 2. Small drill guide into cannula. Drill through bone, nail slot and far cortex. Slot finder is not used for proximal interlock.
- 3. Insert large drill guide.
- 4. Step drill is used to enlarge hole in near cortex. Do not extend to slot in nail.
- 5. Depth guide inserted, drill guide removed and measurement for screw done.
- 6. Screw inserted.—usually 2 screws needed for hole & slot closest to knee.
- 7. Check reduction.
- 8. Remove target arm and L handle.
- 9. Irrigate?
- 10. Bone graft fracture from the reamings.

SIGN <u>ANTEGRADE FEMORAL</u> NAILING TECHNIQUE

Indications

Fractures of the femur in the mid or proximal shaft.

Position of Patient

Supine or lateral. Lateral is best for open reductions; supine for closed reductions. Technique for lateral position will be described. Patient must be stabilized in the lateral position to prevent shifting of the patient.

Reduction

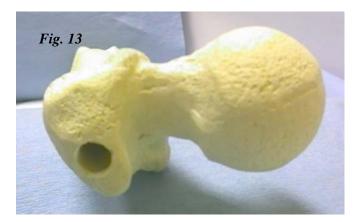
If open reduction, do before skin incision for nail insertion. (See Page 21 for open reduction ideas). Ream distal fragment. Save bone from reamer flutes and bone that comes out when reamer removed. Do not ream through cortex of upper femur (piriformis fossa).

Skin Incision

Posterior and superior to greater trochanter.

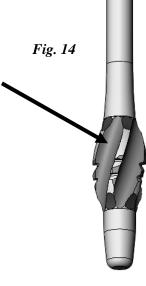
Bone Entrance

Nails with bends or curves should be placed through the greater trochanter, <u>not</u> the piriformis fossa, to decrease the stress to the femoral neck. The entrance for SIGN nail is at the junction of the posterior and middle third of the tip of the trochanter. Bone awl makes the original entrance (Fig. 13).



Reaming

Small reamer used to connect bone entrance and canal. Use progressive size reamers until chatter for 6 cm of the canal. Diameter of nail used is 2 mm smaller. Save bone from reamer for graft (Fig. 14). Ream to 4 mm larger in the metaphysis of femur to accommodate bow of nail. Check reduction during reaming.

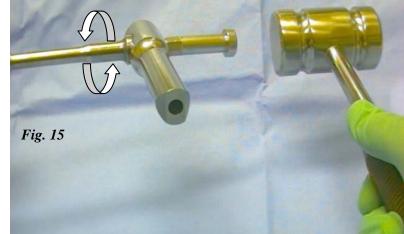


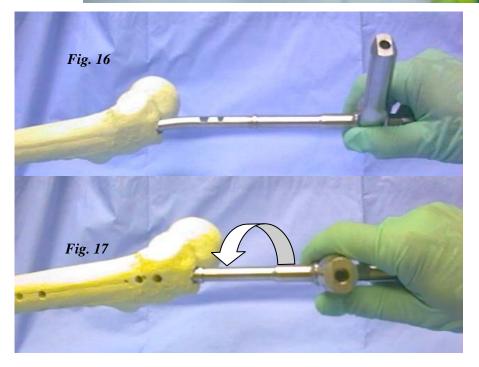
Insert Nail

Use tissue protector to keep nail from contact with the skin.

- 1. Push the nail in as far as possible and then use "tap, tap turn 10° ". The blows to the locking bolt should be small taps so nail will not get caught in the canal (Fig. 15). If the nail becomes tight in the canal and must be removed, use the extractor. **Never hit the L-handle** or interlocking will be impossible. Large blows to the locking bolt bend the nail. The 10° rotation allows the end of the nail to create a larger canal due to the 1.5° bend at the end of the nail. Check reduction as the nail is being advanced in the canal.
- 2. As the nail advances, allow it to rotate as it will (Fig. 16). Proximal interlock can be directed lateral to medial or anterior to posterior.
- Use light taps and twist 10° after each third or fourth tap. The end of the nail has a 1 1/2 degree bend to prevent penetration of the canal wall. Rotate only 10°. If you hit the nail hard it will bend and make distal interlocking difficult. Consider how much force you had used to place a nail when you are placing the distal interlock hole. You may have to adjust the distal

hole if the nail bends on the narrow part of the femur

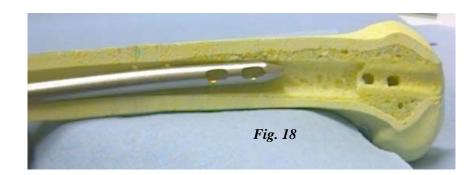




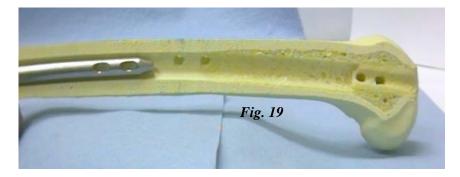
- 4. Final insertion may rotate as bend of nail enters femur (Fig. 17).
- 5. Allow this rotation to occur and interlock depending on where nail lies.

Distal Interlock

1. The final location of the slots in the distal nail depends on the curve of the femur and the force necessary to insert the nail. SIGN nail is a straight nail. If it is inserted into the canal without a great deal of force it will end up in the anterior portion of the femur (Fig. 18). The longer the nail, the more anterior the tip of the nail will be. The target arm may have to be adjusted to accommodate bend of the nail.



2. If the nail is exerted with force it will bend and be more centrally located in the canal (Fig. 19). If the slots are in a narrow part of the femur, they will be more central in the canal.



(See insertions into femur by retrograde approach for further interlocking suggestions, Pages 23-28).

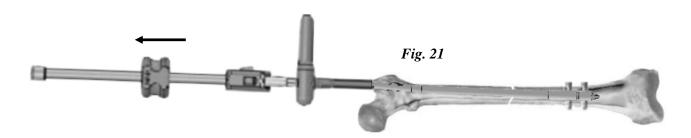
3. Look at reduction to see if it needs impaction. If so insert the nail more deeply into the trochanter as it will become more prominent after impaction.



Fig. 20

Impact Fracture

If the fracture needs impacting, the connector is applied to the locking bolt. The extractor rod containing the slap hammer weight is then attached to the connector. Impaction of the fracture is done after the distal interlock.



Proximal Interlock

1. For proximal interlock see tibia or retrograde femur approach in earlier pages.

(Fig. 20) illustrates posterior and anterior directions.

- 2. Bone graft the fracture from the reamings that came from the flutes of the reamer.
- 3. Close the incisions.
- 4. Manipulate knee to full flexion.

SIGN FIN NAILS

DESCRIPTION: SIGN Intramedullary Fin nails and screws are designed to provide fixation of femoral and humeral fractures without the use of distal interlocking screws.

INFORMATION FOR USE: The surgeon must select the type and size that best meets the patient's requirements. SIGN recommends the following Fin nail 7 - 8mm Dia., 190mm, 240mm. 9 - 12mm Dia., 240mm, 280mm.

INDICATIONS: The SIGN Fin nail is indicated for internal fixation of stable fractures in the femur and humerus.

CONTRAINDICATIONS: Active or latent infection. Wounds in the leg or arm should be closed and dry. Osteoporosis, insufficient quantity or quality of bone/soft tissue. Patients who are unwilling or incapable of following postoperative care instructions.

INTRODUCTION

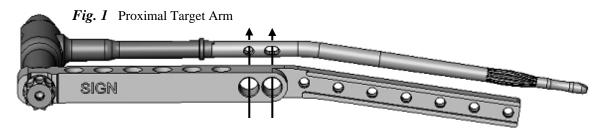
Placement of the distal interlocking screw is the most difficult part in all IM Nail interlocking screw systems. The Fin nail is designed with a fin (Fig. 3) to accomplish fixation in the distal part of the nail. The Fin nail is used for stable fractures.

X-RAYS

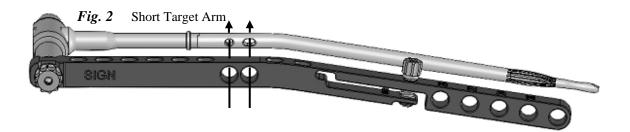
X-rays should include the entire femur or humerus on the same film to measure the nail size indicated. The diameter of the fins on the nail should be a little larger than the medullary canal where the fin will be located. Nail size templates are provided to help determine the size needed.

The fins of the Fin nail should rest in the smallest part of the femoral medullary canal at least 10cm from the fracture.

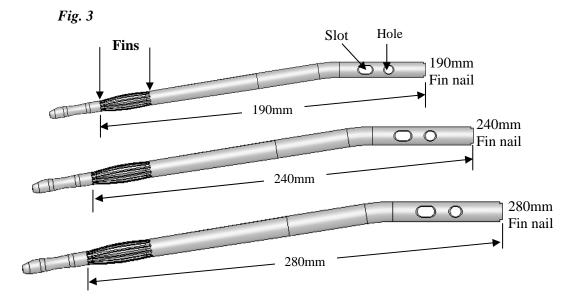
Target Arms



The nail slots can be located with the proximal target arm (Fig. 1) or the short target arm (Fig. 2).



Fin Nails

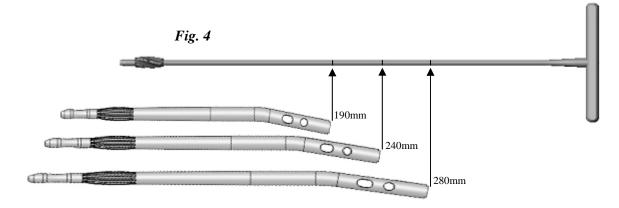


Choosing the Proper Nail

Choosing the proper nail is at the discretion of the surgeon. SIGN is now manufacturing 7 - 8mm Dia., 190mm, 240mm length and 9 - 12mm Dia., 190mm, 240mm, 280 mm length Fin nails for use in femur and humeral fractures (Fig. 3).

<u>NOTE</u>: The nail length, such as 190mm, refers to the distance between the nail notch (at the proximal end of nail) and the end of the flutes, as shown above (Fig. 3).

Reamers used with Fin nails



SIGN reamers are designed with marks at 190mm, 240mm and 280mm (Fig. 4) and (Fig. 6). The marks show the reaming depth of the <u>LAST</u> reamer used for the corresponding nail.

SIGN FIN NAIL (RETROGRADE FEMORAL)

Thoughts prior to surgery

- Indications for Fin nail
- Location
 - The ideal fracture for Fin nail use is a stable femur fracture at least 10 cm from the location where the fins will rest in the narrow part of the femoral canal. The Fin nail may be placed antegrade or retrograde.
- Fracture Type
 - The ideal fracture is a transverse with rotational stability.

The nail should not be placed unless the wounds are clean and can be closed. The preparation x-rays, antibiotics, operating room equipment, and SIGN equipment necessary for insertion of the SIGN Fin nail are discussed earlier in this guide.

Surgical Technique

The patient preparation, OR preparation, incision and entry point are all similar to the standard SIGN nail technique.

Patient Preparation

The usual precautions to avoid infections are observed. Retrograde femur nailing is done in the supine position.

OR Preparation

If the patient has 60° of knee flexion, use a cloth bump made of drapes and gowns and place under the thigh. Do not press on the popliteal structures.

If the patient does not have 60° of flexion, but has 30° of knee flexion, the entrance hole can be made with a step drill and enlarged with reamers or an awl.

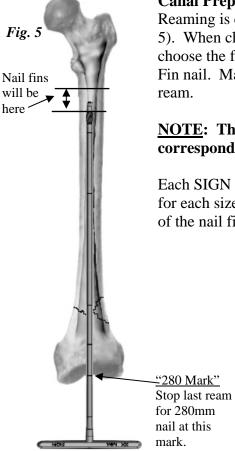
Incision

If open reduction is done, two incisions are used. The first incision is a lateral incision for open reduction. The other is a median parapatellar incision or incision through patellar tendon. The median parapatellar incision gives better visualization of the entrance hole. The entrance hole must be visualized.

If the patient has a fractured tibia and femur on the same side the tibia and retrograde nail are used through an incision through the patella tendon. The tibia fracture should be stabilized first.

Entry Point

Optimal entry point is just anterior to the posterior cruciate ligament. Use a curved awl or other sharp hand instrument to make the initial hole. Use the 7mm pilot reamer to extend from entrance hole into the canal.

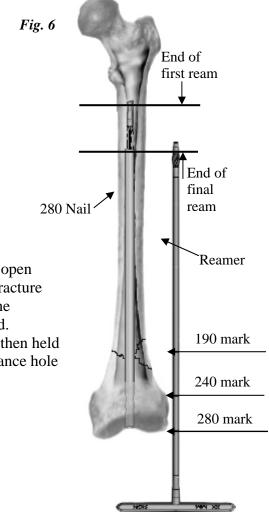


Canal Preparation

Reaming is done as in the standard nail technique, except for the final ream (Fig. 5). When chatter is reached by progressive enlargement of the canal it is time to choose the fin nail size. The final reamer will be the same size as the fins on the Fin nail. Marks provided on the reamers (Fig. 4) determine the depth of the final ream.

<u>NOTE</u>: The final reaming stops where the distal end of the reamer flutes correspond to the proximal end of the fins of the nail see (Fig. 5).

Each SIGN reamer is marked (Fig. 4) and (Fig. 6) for the correct final ream depth for each size Fin nail. The diameter of the last reamer is the same as the diameter of the nail fins.



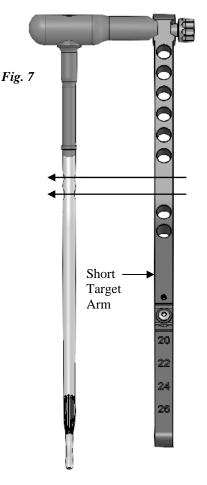
Nail Insertion Steps

Open Reduction

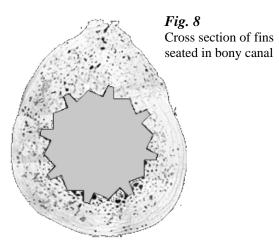
If the fracture is over seven days or a C-arm is not available, open reduction is necessary. A lateral incision at the level of the fracture site is used. The fracture is exposed and hand reaming is done through both fracture fragments. The fracture is then reduced. Correct rotational alignment is essential. The fracture site is then held by bone clamps. The final ream takes place through the entrance hole to establish the depth the reamer goes.

Nail Insertion

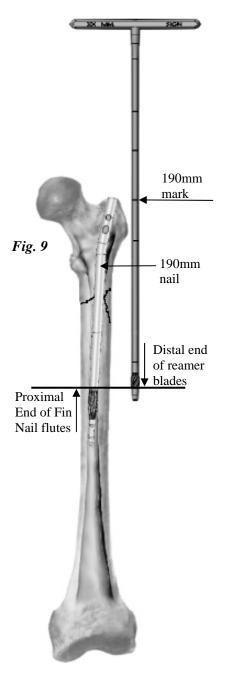
- Insertion of the nail is done by first attaching the nail to the L-handle (Fig. 7). Place the locking bolt through the L-handle and thread it into the nail. Insure that the notches on the nail align with the tabs on the L-handle before tightening the bolt using the combination hex wrench.
- Attach the short target arm or proximal target arm to the Lhandle making sure the bend in the arm corresponds to the bend in the nail.
- Remove the target arm from the L-handle.
- The nail is then inserted into the bony canal by <u>multiple</u> <u>gentle taps</u> with a mallet. The bow in the nail is directed anteriorly. Rotation is not used, when inserting the fin nail.



- Once the nail is seated (Fig. 8) at the proper level in the bony canal, the target arm is reattached to the L-handle.
- Place the cannula and small drill guide through the first hole in the target arm. Using the small drill bit, drill a hole through the near and far cortex of the bone.
- Replace the small drill guide with the large drill guide in the cannula and using Step drill, enlarge the hole through the near cortex.



- The cannula is left in and the depth gauge is used to measure the distance between the outside of the far cortex and the outside of the near cortex. Place the depth gauge through the far cortex, then pull back until the end of the depth gauge catches the outside of the far cortex, then read the measurement on the gauge nearest the end of the cannula.
- The proper screw is selected and screwed into the near cortex, through the nail and into the far cortex. Be sure to leave the ends of the screw proud for later removal.



SIGN FIN NAIL (ANTEGRADE FEMORAL)

(Fig. 9)

If C-Arm is available and the fracture is fresh enough for closed reduction the patient may be in supine or lateral position on a fracture table.

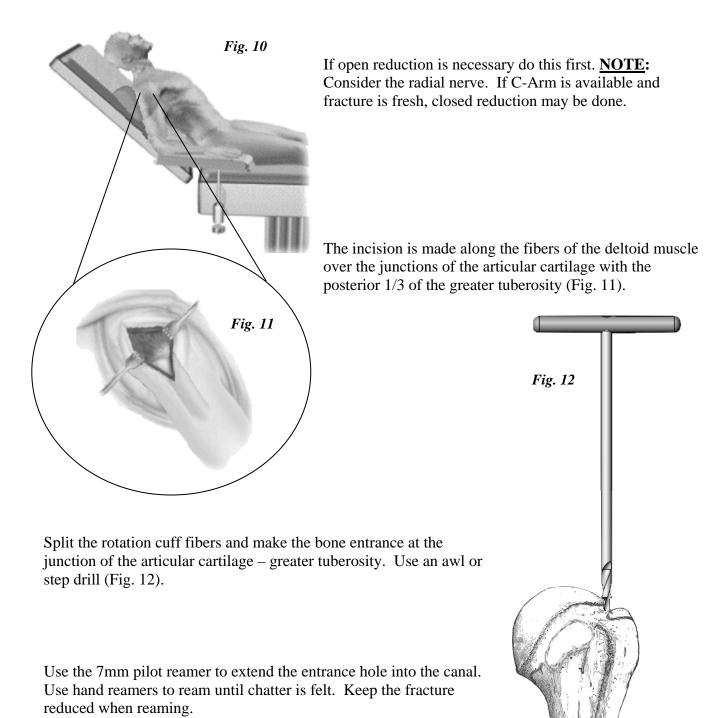
Incision

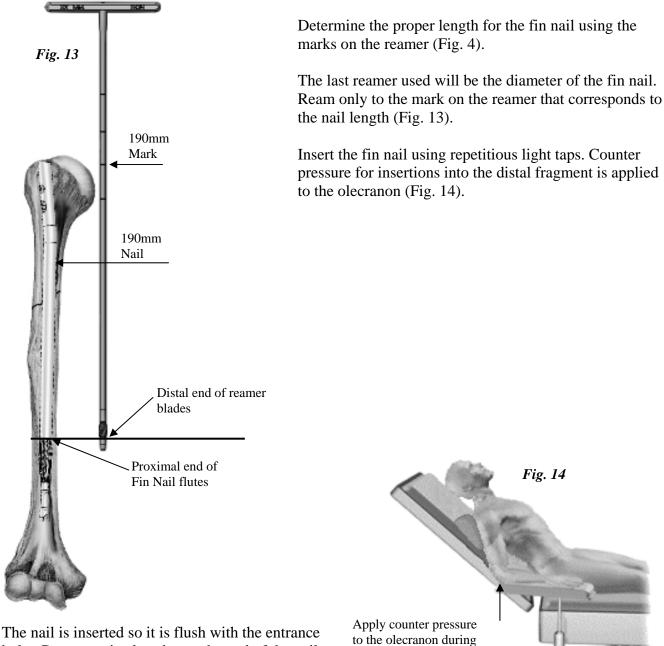
The incision allows approach to the mid-posterior tip of the superior greater trochanter. The greater trochanter is identified and a sharp instrument (awl) is used to make the entrance hole in the mid-posterior plane of the tip of the superior greater trochanter. The curved awl is used to enlarge the entrance hole. The 7mm pilot reamer reams to the canal. Reaming is done after the fracture is reduced as described in the retrograde approach. As the nail is tapped into place, allow the nail to rotate as it proceeds down the canal.

If the fracture must be reduced open or C-Arm is not available or if the fracture is over seven days old, the patient is placed in a lateral position. This makes open reduction as well as nail insertion easier than in supine position. Be sure the patient is stabilized in the lateral position. If open reduction is required, do this first. Ream the femoral canal through the fracture site, as in the retrograde procedure, until the reamer chatters. Proceed as in retrograde nailing for the final reaming and nail insertion.

SIGN Fin Nail with humerus.

The patient is placed in beach chair position on the OR table (Fig. 10). All prominences and areas of potential nerve compression are padded.





hole. Bone wax is placed onto the end of the nail when the L-handle is removed. Check final stability and reduction of the fracture (Fig. 14).

insertion of nail into distal fragment.

ADDITIONAL NOTES

- If the fracture you are treating is more than one week old, open reduction is usually necessary
- Soft tissue damage determines the speed of fracture healing as much as bone damage. Debridement must remove all dead tissue. Do not implant the nail if there is a question of infection.
- If the bone protrudes through the muscle, the fracture absorbed great force, and there is much soft tissue damage. Consider this when debriding.
- Save bone from reaming or take bone from the entrance hole for bone grafting.
- Sometimes casting or splinting after SIGN nail insertions is necessary for unstable fractures. Weight bearing is encouraged in stable fractures. Crutches are used depending on pain.
- Fracture healing is a race between bone healing and implant failure. Therefore, if healing is delayed past 3 months, consider bone grafting.
- Implant removal should be delayed for 24 months. If the nail is removed, protect the bone by crutch for 6 to 8 weeks after removal.
- Use crutches post-op for six weeks with weight bearing determined by the surgeon. The more comminuted the fracture, the longer full weight bearing is delayed. Other factors include how much the cortex is opposed by both sides of the fracture. If 50% opposition of fracture fragments, early weight bearing is OK. Full weight bearing should be delayed in many fractures until callus formation is adequate.
- If you have a comment, problem or something to share with SIGN surgeons around the world, please e-mail or place it in the comment section of the database.



Long Bone Fracture Data Collection Sheets For Data Entry In The SIGN Surgical Database <u>www.signsurgery.org</u>

PATIENT CASE INFORMATION: (All fields are required unless otherwise noted.)							
Patient Name:	Age:	Gender:	Injury Date:				
Hospital Name:	Case Number: (optional)						
Optional Patient Contact Information: (This information will be available only to the applicable hospital).							
Address:							
Phone Number:	Email Address:						

SURGERY INFORMA	TION: Copy this page for each additional surgery for this patient.
Date (month/day/yea	ar):
1. Antibiotics Used?	
	Duration of Antibiotic Coverage: hours days
2. Surgery Comments	S:
	<u> </u>

LONG BONE FRACTURE INFORMATION: (Copy pages 3 - 4 for each additional fracture.)					
Patient Name:					
Case Number:					
1. Fracture Side:	🗌 Left 🛛 Right				
2. Surgical Approach:	 Tibia Antegrade Femur Other: 	Retrograde Femu Antegrade Humer			
3. Location of Fracture: (check all that apply)	Proximal Segmental	Middle Femoral Neck	Distal Intertrochanteric		
4. Type of Fracture:	☐ Closed☐ Gustilo I☐ Gustilo II	☐ Gustilo IIIa ☐ Gustilo IIIb ☐ Gustilo IIIc			
5. Time from injury to De	bridement:hours	days			
6. Time from injury to Sk	in Closure:days				
7. Method of Wound Clos (check all that app		Skin Graft 🛛 🗌 Other:	Muscle Flap		
8. Nonunion:	Yes No				
9. Previous Implant Used If Yes, check all that app If External Fixation	bly: ☐ External Fixation ☐ IM Nail 1. How long was ex	 Plate Wire Wiration in place moval of ext. fixation a 	-		
10. Method of Reaming:	☐ None Pow	er 🗌 Hand			
11. Fracture Reduction:	Open Clos	ed			
12. Comments:					

LONG BONE FRACTURE INFORMATION (continued from page 3)

Patient Name:

Case Number:

	200	220	240	260	280	300	320	340	360	380	400	420
Standard Nails	mm											
8 mm												
9 mm												
10 mm												
11 mm												
12 mm												

13. Nail Type Used: (Please mark the type of nail used to treat this fracture.)

	160	190	240	280
Fin Nails	mm	mm	mm	mm
7 mm				
8 mm				
9 mm				
10 mm				
11 mm				
12 mm				

14. Screw Quantities Used: (Please enter the quantity of each type of screw used with this nail.)

Length in mm	25	30	35	40	45	50	55	60	65	70	75
#Proximal											
#Distal											

Proximal Screw Holes	Distal Screw Holes

15. X-Rays Taken: (Please list the names of the digital image files for all x-rays of this fracture.)

Digital Image X-Ray File Name(s)	Pre-Op	Post-Op	Date Taken

Notes on uploading digital image x-ray files:

- 1. This table is provided for you to keep track of digital x-ray images so that the process of uploading these images to the online database goes smoothly.
- 2. The time required to upload image files is determined by the size of your digital image files and your internet connection speed.
- 3. <u>VERY IMPORTANT: You can reduce the size of your digital image files by converting them to</u> <u>grayscale (remove all color) and by reducing the dimensions of your pictures to approximately 640 x</u> <u>480 pixels. Many digital cameras come with software programs capable of these tasks.</u>

FOLLOW-UP I	NFORMATION: (Copy this s	heet for each additio	nal follow-up.)			
Patient Name:						
Case Number:		Date (mor	nth/day/year):			
If multiple frac	tures, which fracture is th	nis a follow-up for	?			
1. Infection:	 ☐ Yes ☐ No If yes: Incision of the wound: Infection depth: Duration of infection: ☐ Osteomyelitis 	 ☐ Yes ☐ Superficial weeks ☐ Amputation 	No ☐ Deep (patient returns to surgery)			
3. Partial weig	ht bearing:	🗌 Yes	No			
4. Painless ful	I weight bearing:	🗌 Yes	No			
5. Healing by 3	k-ray:	☐ Yes	No			
	n greater than 90 oplicable for Hip Fracture)	☐ Yes	No			
7. Screw breal	kage:	☐ Yes	No			
8. Screw loose	ening:	☐ Yes	No			
9. Nail breaka	ge:	🗌 Yes	No			
10. Nail looser	ning:	🗌 Yes	No			
11. Deformity:	If yes: Alignment:	r 10 degrees) 10 degrees varus 20 degrees varus	 Over 10 degrees valgus Over 20 degrees valgus 			
	Rotation: Over	30 degrees				
12. Repeat Surgery: Yes No If Yes, check all that apply: For Infection For Deformity For Non-union						
	Union, check all that apply	Exchange Nail Bone Graft				
13. Comment	ts:					

14. X-Rays Taken: (Please list the names of the digital image files for all x-rays during this follow-up.)

Digital Image X-Ray File Name(s)	Date Taken

NOTES

